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09/816,641	03/22/2001	Daniel Jacobs	235692000121	6872

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/816,641	<b>Applicant(s)</b> JACOBS ET AL.	
	<b>Examiner</b> Kathryn Odland	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10-19,21,23-26 and 46-61 is/are pending in the application.
- 4a) Of the above claim(s) 4-7,10,14,15,17,19,23,51-53 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,11-13,16,18,21,24-26,46-50 and 54-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>(1,2,4,10)/02&amp;6/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 4-7, 19, 23, 51-53 and 59-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 4, 2004. Further, claims 10, 14, 15 and 17 do not read on the Species elected and have also been withdrawn.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what applicant intends in the phrase, "a plurality of attachment points that are varied in density on the backing." Is applicant referring to the tapers of the tines?

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 13, 16, 18, 21, 24-26, 48, 50 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. in US Patent No/ 5,352,229.

Regarding claim 1, Goble et al. disclose an implantable tissue approximation device (Bone can be considered a form of hard tissue. Nonetheless, functional language is not given patentable weight in apparatus claims and the device of Goble et al. is capable of performing the function). The device has a supportive backing (31) having at least one through-hole (such as 33, 34) formed therethrough and at least one attachment point (35) extending from the backing, as recited in column 5, lines 55-68 and column 6 and seen in figure 2.

Regarding claim 2, Goble et al. disclose that as applied to claim 1 as well as a backing that has a shape in the form of an H, as seen in figure 2.

Regarding claim 13, Goble et al. disclose that as applied to claim 1 as well as a backing that is a solid material.

Regarding claim 16, Goble et al. disclose that as applied to claim 1 as well as a least one attachment point that includes a shape and direction selected from the group consisting of canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines, as seen in figure 2.

Regarding claim 18, Goble et al. disclose that as applied to claim 1 as well as a backing further having a front side and a back side and wherein the at least one attachment point extends from the front side, as seen in figure 2.

Regarding claim 21, Goble et al. disclose that as applied to claim 1 as well as at least one attachment point that includes a plurality of attachment points and wherein the at least one through-hole is disposed between the attachment points, as seen in figure 2.

Regarding claim 24, Goble et al. disclose that as applied to claim 1 as well as a supportive backing that is rigid.

Regarding claim 25, Goble et al. disclose that as applied to claim 24 as well as a supportive backing that has a strength sufficient to set fragmented bones, as recited in columns 5, 6 and seen in figure 2.

Regarding claim 26, Goble et al. disclose that as applied to claim 1 as well as a supportive backing that defines at least one through hole and includes a plurality of through-holes formed through the supportive backing, as seen in figure 2.

Regarding claim 48, Goble et al. disclose that as applied to claim 1 as well as a backing that is curved, as seen in figure 2, where in the areas of 32 are curved. Further the

Art Unit: 3743

device itself has some curvature. Moreover, the claim does not limit in what way the device is curved.

Regarding claim 50, Goble et al. disclose that as applied to claim 18 as well as a backside of the backing is concave, as seen in figure 2, there is some degree of concavity.

Regarding claim 54, Goble et al. disclose that as applied to claim 1 as well as at least one attachment point that includes a plurality of attachment points that are interspersed among the plurality of through-holes, as seen in figure 2.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11, 12 and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. in US Patent No. 5,352,229.

Regarding claims 11 and 12, Goble et al. disclose that as applied to claim 1. Further, Goble et al. disclose that as recited in claim 13. Claim 13, recites a solid backing material. Thus, this is considered an equivalent to a backing comprises porous material. Further, a porous material comprises a mesh, net, or lattice is part of this equivalence.

Regarding claims 55-58, Goble et al. disclose that as applied to claim 1. However, Goble et al. do not recite a device having at least one therapeutic agent. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate any of a plethora (such as proteins, pharmaceuticals, genetic material) of therapeutic agents to the device where the agent is impregnated/coated for the purpose of promoting healing. Moreover, the current application on page 52 merely recites, "The device **may** further contain bioactive compounds or therapeutic agents." Therefore, criticality has not been established.

9. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. in US Patent No. 5,352,229 in view of Tschakaloff in US Patent No. 5,779,706.

Regarding claim 49, Goble et al. disclose that as applied to claim 1. However, Goble et al. do not recite a device is configured such that it is shapeable intra-operatively for use in a patient's body. However, the current application specification on

page 52 merely recites, "The device **may** also be made of material and thickness such that it may be shaped intra-operatively to the patent's anatomy..." Thus, applicant has failed to establish criticality for such a feature. Nonetheless, Tschakaloff teaches intra-operatively shaped devices. Thus, it would be obvious to one with ordinary skill in the art to have the device capable of intra-operative shaping for the purpose of proper fit.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 2, 11-13, 18, 21, 24-26, 46-50, 54 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Tormala et al. in US Patent No. 6,350,284.

Regarding claim 1, Tormala et al. disclose an implantable tissue approximation device having a supportive backing (such as 2) having at least one through-hole (at 5) formed therethrough and at least one attachment point (such as via 3) extending from the backing. The web layer can be considered a point of attachment since it promoted growth. See columns 3-4 and figure 1.

Regarding claim 2, Tormala et al. disclose that as applied to claim 1 as well as a backing that has a shape in the form of a C as seen in figure 1.



Regarding claim 11, Tormala et al. disclose that as applied to claim 1 as well as a backing having porous material extending therefrom.

Regarding claim 12, Tormala et al. disclose that as applied to claim 11 as well as a porous material comprises a mesh, net, or lattice, as recited in columns 3-4 and seen in figure 1.

Regarding claim 13, Tormala et al. disclose that as applied to claim 11 as well as a backing (2) of a solid material, as recited in columns 3-4.

Regarding claim 18, Tormala et al. disclose that as applied to claim 1 as well as a backing further having a front side and a back side and wherein that at least one attachment point (3) extends from the front side, as seen in figure 1.

Regarding claim 21, Tormala et al. disclose that as applied to claim 1 as well as at least one attachment point includes a plurality of attachment points, where element 3 will attach at numerous points, and wherein the at least one through-hole (at 5) is disposed between the attachment points, as seen in figure 1.

Regarding claim 24, Tormala et al. disclose that as applied to claim 1 as well as a supportive backing (2) that is rigid, as recited in columns 3-4.

Regarding claim 25, Tormala et al. disclose that as applied to claim 24 as well as a supportive backing that has a strength sufficient to set fragmented bones.

Regarding claim 26, Tormala et al. disclose that as applied to claim 25 as well as a supportive backing that defines at least one through hole includes a plurality of through-holes (@5) formed through the supportive backing, as seen in figure 1.

Regarding claim 46, Tormala et al. disclose that as applied to claim 1 as well as a device that comprises a material selected from the group consisting of biodegradable and biological materials, as recited in columns 3-4.

Regarding claim 47, Tormala et al. disclose that as applied to claim 46 as well as biological material that comprises one or more materials selected from the group consisting of **collagen**, hydroxyapatite from natural sources, hydroxyapatite from synthetic sources, bone graft and **any polymerized versions or composites thereof**, as recited in column 4, lines 65-68.

Regarding claim 48, Tormala et al. disclose that as applied to claim 1 as well as a backing is curved, as seen in figure 1.

Regarding claim 49, Tormala et al. disclose that as applied to claim 1 as well as a device that is configured such that it is shapeable intra-operatively for use in a patient's body, as recited in column 3, lines 15-25.

Regarding claim 50, Tormala et al. disclose that as applied to claim 18 as well as a backside of the backing that is concave, as seen in figure 1.

Regarding claim 54, Tormala et al. disclose that as applied to claim 1 as well as at least one attachment point includes a plurality of attachment points that are interspersed among the plurality through-holes, as seen in figure 1.

Regarding claim 55, Tormala et al. disclose that as applied to claim 1 as well as a device comprises at least one therapeutic agent, as recited in column 4, lines 48-68 and column 5, lines 1-10.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3743

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 16 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in US Patent No. 6,350,284.

Regarding claim 16, Tormala et al. disclose that as applied to claim 1. However, at least one attachment point includes a shape and direction selected from the group consisting of canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines. On the other hand, applicant is directed to column 4, lines 27-35, which recites that the implant can be affixed with minitacks, microtacks, etc. Therefore, it would be obvious to one with ordinary skill in the art to include additional tines for the purpose of enhanced attachment.

Regarding claim 56, Tormala et al. disclose that as applied to claim 55. However, Tormala does not explicitly recite impregnating/coating the therapeutic agent. On the other hand it would be obvious if not inherent to apply the agent by impregnating and/or coating.

Regarding claim 58, Tormala et al. as modified disclose that as applied to claim 57 as well as at least one therapeutic agent is selected from the group consisting of proteins, pharmaceuticals, genetic material, as recited in columns 3-5.

### ***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 2, 4-8, 10-19, 21, 23-26 and 46-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 41 of U.S. Patent No. 6,645,226. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are a merely a broader recitation than that recited in the patent.

17. Claims 1, 2, 4-8, 10-19, 21, 23-26 and 46-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 7, 9-16, and 19 of U.S. Patent No. 6,485,503. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are a merely a broader recitation than that recited in the patent.

18. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/299,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is merely a reworded representation for the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1, 2, 4-8, 10-19, 21, 23-26 and 46-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 16 of copending Application No. 10/418,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1, 2, 4-8, 10-19, 21, 23-26 and 46-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, and 8 of copending Application No. 10/418,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Conclusion**

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are US Patent No. 4,651,724.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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